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Uterine artery embolisation for the treatment of symptomatic uterine fibroids

Embolizacja tętnic macicznych w leczeniu objawowych mięśniaków macicy

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Key words

uterine fibroids, embolisation

Słowa kluczowe

mięśniaki macicy, embolizacja

S u m m a r y

Introduction. Uterine fibroids are the most common benign uterine tumours which can be treated with conservative, surgery or minimally invasive methods. Selection of patients for embolisation seems to be essential.

Aim. Assessment of efficacy and safety of uterine artery embolisation with hydrogel microparticles coated with an anti-inflammatory agent for reduction in symptomatic uterine fibroid volumes.

Material and methods. In the prospective observational study carried out between January 2011 and December 2013, 206 patients with symptomatic fibroids were qualified for uterine artery embolisation. 118 aged 32 to 51 (average 39), who reported for follow-ups 3-4 months after procedures, were evaluated. According to the number of fibroids, patients with 2/4 fibroids predominated (78 patients), followed by those with single fibroids (25) and with myomatous uteri (14 patients). According to fibroid sizes, 4 groups were distinguished: < 7 cm in 77 patients, 7-12 cm in 19, > 12 cm in 8, and myomatous uteri in 14 patients.

Results. A mean decrease in fibroid volume in the entire study population was 62%, ranging from 9% in the patient with a hyalinised fibroid to 100% in patients with separated submucosal fibroids.

Conclusions. UAE is a safe and effective treatment for symptomatic uterine fibroids. In addition to reducing the symptoms, significantly reduces their volume. The key to success is proper qualification, as well as cooperation between the radiologist and the gynecologist.

S t r e s z c z e n i e

Wstęp. Mięśniaki są najczęściej występującymi łagodnymi guzami macicy. W ramach leczenia stosuje się zarówno metody zachowawcze, chirurgiczne, jak i minimalnie inwazyjne. Kluczowym elementem przy embolizacji jest odpowiednia kwalifikacja pacjentek.

Cel pracy. Ocena skuteczności i bezpieczeństwa embolizacji tętnic macicznych mikrocząstkami hydrożelowymi pokrytymi środkiem przeciwzapalnym w zmniejszaniu objętości objawowych mięśniaków macicy.

Materiał i metody. W prospektywnym obserwacyjnym badaniu od stycznia 2011 do grudnia 2013 do embolizacji tętnic macicznych zakwalifikowano 206 pacjentek z objawowymi mięśniakami macicy. Ocenie poddano 118 kobiet w wieku od 32 do 52 lat (średnia 39 lat), które zgłosiły się na wizytę kontrolną po miesiącu i kontrolne badanie rezonansu magnetycznego po 3 miesiącach. Pod względem ilości mięśniaków przeważającą grupą były chore z 2/4 mięśniakami (78 chorych), następnie z pojedynczymi mięśniakami (26 chorych) i z macicą tzw. mięśniakową (14 chorych). Ze względu na wielkość/średnicę mięśniaków wyróżniono 4 grupy: < 7 cm u 77 chorych, 7-12 cm u 19 chorych, > 12 cm u 8 chorych, macicę mięśniakową stwierdzono u 14 chorych.

Wyniki. Średnie zmniejszenie objętości mięśniaków w całej badanej grupie wyniosło 62%, poczynając od najmniejszej redukcji 9% u chorej z zeszkliwiałym mięśniakiem, po 100% u chorych z wydzielonym mięśniakiem podśluzówkowym.

Wnioski. UAE jest bezpieczną i skuteczną metodą leczenia objawowych mięśniaków macicy. Oprócz redukcji objawów, prowadzi do znacznego zmniejszenia ich masy. Istotną rolę w procesie leczenia odgrywa odpowiednia kwalifikacja chorych do zabiegu i ścisła współpraca między radiologiem zabiegowym i ginekologiem.

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INTRODUCTION

Uterine fibroids are the most common benign uterine tumours, which are also called uterine fibromas; histopathologically they are leiomyomas and are among the most frequently occurring benign neoplasms affecting 20-40% of women above the age of 35 years (1-3). Although some factors affecting their occurrence have been determined, their aetiology remains unknown. They are composed of smooth muscles, the same ones, which build the uterine wall. They assume the form of tumours and can occur individually or in clusters, several or dozen tumours each. Their diameters range from several to 15 cm and more. Generally, their sizes do not exceed 10-12 cm. According to their location, fibroids are divided into subserous (the most common type – 50% of cases), intramural (30%), submucous (much less common) or located in the cervix and the round ligament of the uterus. Every fifth patient with fibroids complains of the accompanying symptoms, such as pain and discomfort in the region of the pelvis minor, profuse and prolonged menstrual bleedings, dysmenorrhoea, fertility disorders and miscarriages. In some cases, due to a mass effect, fibroids can compress the adjacent organs, e.g. the urinary bladder, leading to pollakiuria, incontinence or anuresis. In extreme cases, this benign neoplasm can compress the uterus resulting in urinary retention and hydronephrosis. Only about 20% of patients with fibroids have symptoms qualifying them for treatment.

Uterine fibroids can be treated with conservative and interventional methods. Pharmacological treatment involves hormonally active drugs, mainly gonadoliberein analogues, followed by selective estrogen and progesterone receptor modulators, progesterone antagonists, androgens, pure antiestrogens and aromatase inhibitors. The newest preparation used is ulipristal acetate – a synthetic progesterone receptor modulator approved for preoperative treatment of uterine fibroids. Administered for three months before surgery, ulipristal acetate to reduce the volume of fibroids before their removal. According to literature data, post-conservative treatment recurrences are observed in 30-40% of cases.

The interventional methods include surgical and minimally invasive ones, including embolisation, high-intensity focused ultrasound (HIFU) (sometimes focused ultrasound – FUS), ablation or cryomyolysis (4). The most common surgical procedure is hysterectomy. Depending on the extent of procedure, hysterectomies can be partial (removal of the body of uterus), total, total with tuboovariectomy or radical – in cases with neoplastic lesions.

Hysterectomy is usually associated with suppressed menstruation due to the lack of uterine mucous membrane, which is located in the uterine body. In cases of ovariectomy, premenopausal women develop surgically induced menopause with its typical symptoms.

One of the sparing methods is myomectomy, i.e. removal of fibroid tumours while the uterus is preserved,

which is an alternative to hysterectomy. The objective of myomectomy is to preserve the reproductive abilities of women and to alleviate some symptoms, such as profound menstruations, pain or compression-associated symptoms. The fibroids > 6 cm are considered too big to be treated by laparoscopy. During the 10-year post-myomectomy period, recurrences are found in even 27% of cases. The traditional procedures can be performed during laparotomy, laparoscopy or via the transvaginal route (5). At the end of the 20th century, uterine artery embolisation (UAE) was introduced, which is the method of low invasiveness. In the 80ties, during UAE for the treatment of reproductive tract haemorrhages, the procedures were found to stop haemorrhages but also substantially reduce fibroid sizes, which was described for the first time in 1987 (6). The first publication regarding the treatment of fibroids with uterine artery embolisation was published in France in 1994 (7). The major assets of such procedures are their low invasiveness, high efficacy, avoidance of surgical intervention, hence preservation of the uterus. Therefore, women started to be increasingly interested in this method, which success was associated with many positive elements. Today, UAE is one of the most commonly applied methods to treat uterine fibroids (8). It is estimated that in 95% of women with symptomatic fibroids recognised during imaging examinations, there is a technical possibility to perform embolisation. Menstruating women with diagnosed symptomatic fibroids are qualified for UAE, irrespective of tumour size and number. However, the fibroid diameter and location enable to estimate the risks and anticipated outcomes.

Selection for embolisation

The prerequisite of effective and safe embolisation is good cooperation between interventional radiologists and gynaecologists. The gynaecologist first decides whether a particular patient qualifies for any further treatment as only about 20% of patients have symptomatic fibroids, and only they are good candidates for treatment.

The first-line imaging examination is transvaginal US, followed by MRI necessary for radiological evaluation (9). MRI is to exclude pathologies other than fibroids within the pelvis (10). Moreover, the endometrium has to be examined; aspiration biopsy according to the Pipell method is used. Cervical cytology and vaginal bacteriological tests are also recommended.

The main laboratory examinations include blood cell counts, coagulation tests (INR, APTT) and renal (creatinine, urea) concentration of FSH at cycle day 3, SR and CRP, general urine tests and ROMA tests. The procedures of embolisation are performed until cycle day 10 (4).

Indications and contraindications for embolisation

According to the Society of Obstetricians and Gynaecologists of Canada, each patient with symptomatic

fibroids without contraindications for embolisation can be a candidate for the procedure in question, if benefits, i.e. post-procedure subsidence of symptoms exceed the risk of complications (11). Noteworthy, minimally invasive embolisation of uterine fibroids is associated with low numbers of serious complications; therefore, benefits exceed risks in the majority of cases.

The key element is to make sure that the symptoms reported are caused by fibroids and not some other pathology. Before the selection for embolisation, the uterine cavity and the source of abnormal bleeding should be accurately assessed. If the bleeding is caused by a single, small-sized subserous fibroid, hysteroscopic myomectomy should be considered.

MRI is more advantageous for evaluation of uterine fibroids than ultrasound examinations, particularly for the diagnosis of adenomyosis; unfortunately, the major drawback is its poor availability (11).

With the years, the value of UFE in the treatment of adenomyosis has been increasingly high. According to the Canadian guidelines, UFE can be performed in patients with concomitant adenomyosis and fibroids. The number and size of fibroids is not a contraindication for UAE procedures. During one procedure, all lesions are treated. Decisions regarding UFE treatment should be made individually, considering benefits vs. risks. The number of contraindications is relatively low. The absolute contraindications include pregnancy, cancer, infections of the reproduction tract, pelvis or systemic infections. The relative contraindications involve allergy to iodine contrast media, renal failure, fibroids of narrow stalks, and intrauterine devices.

Large, pedunculated fibroids, both subserous and submucosa, carry the risk of necrosis with resultant infection (12). The literature data indicate that in this kind of management surgery is required in 1-5% of such cases (13, 14). According to the German publication, one of relative contraindications is the use of gonadoliberein analogues for more than 3 months (4). The opinions on embolisation in patients with adenomyosis are inconsistent; the majority of them follow the guidelines of the Canadian Society. A special case is women with adenomyosis who want to preserve the uterus. For such patients, UAE is one of few options of non-invasive treatment. Therefore, UAE should be considered in such special situations (15-19).

When UAE procedures are performed without epidural anaesthesia, the majority of patients are likely to develop the post-embolisation syndrome, which is a characteristic reaction of the body associated with acute, transient ischaemia of the uterine muscle. The possible symptoms include pain, nausea and vomiting, moderately elevated temperature not exceeding 37.5°C (7).

The comparison of post-hysterectomy and post-embolisation complications reveals that severe, life-threatening complications develop mainly after hysterectomy (14.8% hyst vs. 4.5% UAE) while the percentage of slight complications is comparable in both

groups (23.5% vs. 21.0%); premature menopause occurs in 1.4% of cases in the UFE group compared to 0.2 in the hysterectomy group (20). The incidence of premature menopause depends on age, more precisely on the ovarian reserve. With the extent of potential connections between the uterine and ovarian artery determined, embolisation materials of larger diameters are used, which ensure a wider margin of safety. The embolisation particles currently available on the market are characterised by excellent calibration; thus, the most suitable material can be chosen. According to the current findings, premature menopause occurs in 15% of women aged > 45 years and < 1% in women aged < 45 years (21). One of the studies evaluated the ovarian reserve in 36 women over the period of 5 years. All patients were of reproductive age who reported symptoms associated with uterine fibroids and were qualified for uterine artery embolisation. The study demonstrated that embolisation procedures affected accelerated decreases in ovarian reserves (22).

In another study assessing the treatment outcomes in 177 women, the conclusions were different. The study included only women before menopause (the mean age – about 40 years). The authors evaluated the effect of uterine artery embolisation (88 women) and hysterectomy (89 patients) on the ovarian reserve. The 24-month observations revealed a significant increase in FSH in both methods. Additionally, the level of anti-Müllerian hormone (AMH) was determined in 30 patients after UAE and in 33 after hysterectomy. A significant decrease in AMH was observed in patients after UAE. The above data led to the conclusion that both methods affect the ovarian reserve, which can result in premature (iatrogenic) menopause (23). Many studies evaluated the percentage and types of connections between the uterine and ovarian artery. In the study by Razavi et al. (24) of 2002, the uterine-ovarian connections were classified into 3 types: type I (21.6%) – inflow through the ovarian artery to the uterine artery via anastomoses, type II (3.9 %), in which the ovarian artery directly supplies the fibroid and type III, in which the ovaries are mainly supplied by the uterine artery. In type I and II, unless the procedure is carefully carried out, embolisation can be incomplete, whereas in type II, inattentive embolisation can lead to ovarian injury. Once the statistical extent of those connections is known, a suitably larger material can be used, which will minimise the percentage of complications (fig. 1A, B).

In still another study, the effects of both procedures on premature ovarian function extinction were evaluated. The study population included 96 patients. According to the findings, none of the methods – embolisation or surgical interventions (hysterectomy, myomectomy) showed significant effects on the ovarian reserve (25). The results of the studies available do not explicitly decide about the main objection to UFE, i.e. premature menopause. Provision of information regarding not only potential peri- and early post-procedure side effects but also possible remote adverse effects is essential.

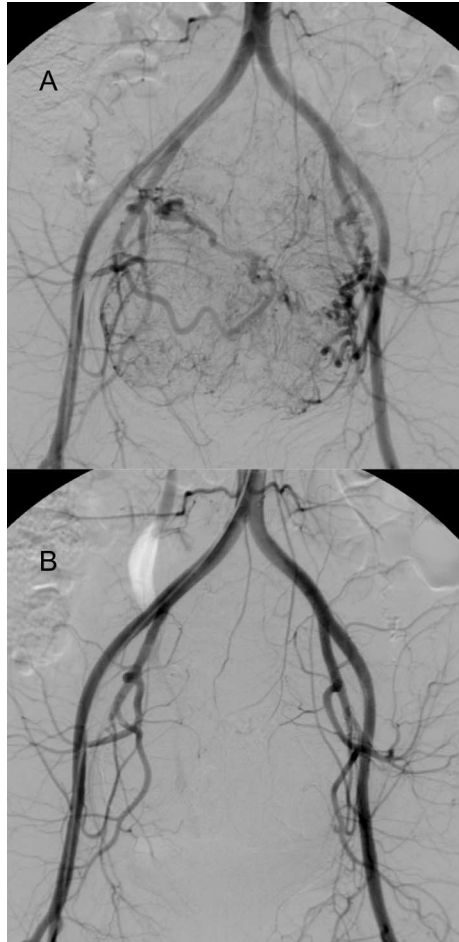


Fig. 1. Uterine artery embolisation in the treatment of massive symptomatic uterine fibroids. Angiography before (A) and after (B) treatment.

However, those effects should be considered comparing them to complications after other procedures aiming at elimination of fibroid-induced symptoms. Considering its efficacy and number of complications, UAE seems to be one of the most effective, minimally invasive methods for the treatment of uterine fibroids.

AIM

Assessment of efficacy and safety of uterine artery embolisation with hydrogel microparticles coated with an anti-inflammatory agent for reduction in symptomatic uterine fibroid volumes.

MATERIAL AND METHODS

In the prospective observational study carried out between January 2011 and December 2013, 206 patients with symptomatic fibroids were qualified for uterine artery embolisation. Patients reporting for follow-ups and repeated MRI after 3 months were assessed. During the qualification visit, the following were performed in each patient: history taking, physical examination, blood cell counts, clotting times, renal tests, hormones, B-hCG, cytologies, bacteriological vaginal tests, histopathological examinations according to the Pipell method, transvaginal Doppler US and MRI without paramagnetic contrast. The procedures were performed until the cycle day 10. Both the selection and follow-up examinations were carried out using the Avanto Siemens 1.5T. The evaluation was based on T2-dependent images in the sagittal, frontal and transverse plane and T1-dependent images in the sagittal plane after paramagnetic contrast administration in the turbo spin echo sequence. In cases of follow-up examinations 3 months after procedures, T1-dependent images in the sagittal plane after paramagnetic contrast administration in the turbo spin echo sequence were used. In selected cases, T1-dependent images in the vibe sequence were additionally used with adipose tissue saturation.

Procedures were performed by 5 interventional radiologists with at least several-year experience in embolisation. Under local anaesthesia initial angiography (Seldinger method), was performed through the Pigtail catheter placed right under renal arteries (fig. 2). Selective catheterisation of uterine

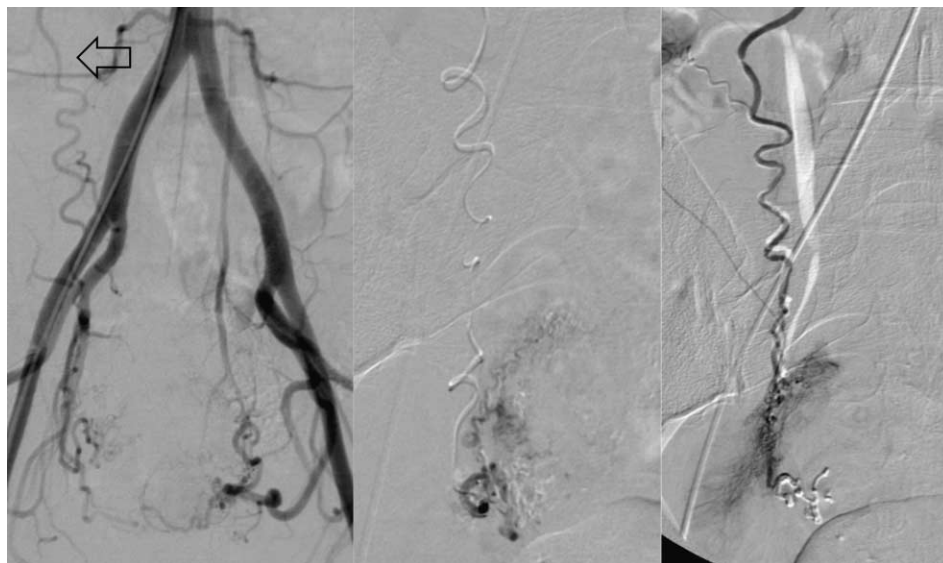


Fig. 2. Angiography visualised the excessively filled right ovarian artery (arrow). After selective catheterization, the ovarian artery was found to supply the uterine fibroid and was dangerously connected with the uterine artery. The connection was closed using the mixture of lipiodol and Gluebrin II. Follow-up angiography demonstrated proper inflow to the right parametrium and lack of connection with the uterine artery.



Fig. 3. Images of three different patients. On the left – MRI before the procedure; on the right – 3 months after the procedure. Upper images – classic fibroid volume reduction, middle images – the fibroid is slowly released by contact with the uterine cavity, bottom images – the fibroid is completely separated.

arteries was carried out using a 0.035 hydrophilic guide wire (Radifocus Guidewire, TERUMO) and a 5 Fr RUC catheter (Roberts Uterine Catheter, COOK). In cases of difficult catheterization of uterine arteries, a 2.7 Fr Progrete microcatheter (TERUMO) was applied. Our material shows that the use of a microcatheter was necessary in at least every fourth woman. The spherical, calibrated Embosphere particles, 700 μ m (CELONOVA) were used for embolisation. When connections between the uterine and ovarian artery were visible on initial angiography, they were closed with the use of 900 μ m particles.

The lack of blood inflow to uterine arteries and contrast ballotement in the uterine artery were considered the technical success. The efficacy of embolisation was assessed one month after the

procedure using transvaginal US and 3 months after the procedure on the follow-up MRI.

RESULTS

From 206 patients involved, 118 aged 32 to 51 (average 39), who reported for follow-ups 3-4 months after procedures, were evaluated. According to the number of fibroids, patients with 2/4 fibroids predominated (78 patients), followed by those with single fibroids (25) and with myomatous uteri (14 patients). Intramural and subserous fibroids prevailed; 23 patients had submucosal fibroids. According to fibroid sizes/diameters, 4 groups were distinguished: < 7 cm in 77 patients, 7-12 cm in 19, > 12 cm in 8, and myomatous uteri in 14 patients. In cases of single fibroids, their diameter was measured. In the group with 2/4 fibroids, the results were averaged; in the cases of

myomatous uteri, the longitudinal uterus sizes were measured. Changes in fibroid sizes were evaluated based on their volume, where the radius was half of the largest fibroid diameter. For instance, a fibroid 8.8 cm in diameter and 93 cm³ in volume, decreased to 5.6 cm in diameter, which corresponds to the volume of 350 cm³ (volume reduction by 74%). Fourteen out of 23 patients delivered submucosal fibroids, which was considered a 100% reduction in volume. A mean decrease in fibroid volume in the entire study population was 62%, ranging from 9% in the patient with a hyalinised fibroid to 100% in patients with separated submucosal fibroids. In the group with fibroids diameter < 7 cm, the volume decreased by 63% whereas in the group with fibroids diameter > 12 cm by 52%. The least reliable value was a longitudinal dimension reduction in uterus sizes by an average of 24% in patients with myomatous uteri.

In 9 patients, the uterine artery ostia developed spasm during catheterization, which did not allow further catheterization and required nimodipine infusions. In 1 case, the uterine artery was injured with slight extravasation of contrast; the vessel was closed with microparticles. In 1 patient with a submucosal fibroid, hysteroscopic intervention was necessary to evacuate the entirely separated fibroid. 6 months after the procedure in any patient < 46 years of age and in 3 patients > 46 years of age, premature menopause was observed; in the remaining patients the cycles normalised after 3 months, with a substantial reduction in bleeding and shortening of menstruations (fig. 3).

DISCUSSION

The literature contains numerous studies evaluating the efficacy of symptom reduction after classical procedures and embolisation (26).

The Cochrane library published a review of six randomised trials in 732 women (27). Uterine artery embolisation was compared with other methods used for the treatment of symptomatic uterine fibroids, showing no significant differences in patient satisfaction between UAE and surgical procedures. The research was carried out in 516 women over the period of 2 years (OR 0.69, 0.40 to 1.21, 5 trials) and in 295 patients over the period of 5 years (OR 0.90, 95% CI 0.45 to 1.80, 2 trials). One of the studies describing 122 women demonstrated that the level of life improved equally in both groups during one year (mean difference -7.60, -17.55 to 2.35). The individual trials confirmed the efficacy and safety of uterine artery embolisation in the treatment of symptomatic uterine fibroids. Moreover, shortened procedure duration, shorter hospitalisation and quicker recovery were pointed out, compared to conventional procedures. This in turn enabled quicker return to work, hence substantially reduced costs. Additionally, the procedure itself was noted to be associated with significantly lower blood loss. Therefore, the need for any transfusions during the procedures dropped virtually to zero. However, UAE was associated with higher numbers of re-interventions, which resulted in short,

hospitals re-admissions (27). Considering the above, the key to success is cooperation between gynaecologists and interventional radiologists.

The studies comparing the efficacy of the procedure in question revealed that symptoms subsided to a similar degree in both interventional methods. No significant differences in satisfaction and quality of life were found over the period of one and three years after procedures (26).

Uterine artery embolisation for the treatment of symptomatic uterine fibroids performed for over 20 years, is increasingly used. Many European centres apply this method, hence providing full-profile care.

One of the studies involved 8159 women undergoing embolisation procedures. Its findings revealed that re-interventions were necessary in 5.3% of women over the period of 5 years. The risk of severe complications was determined at the level of 2.9% (28). Similar conclusions were formulated in the study by Tropeano and colleagues (29). According to their publication, 15% of patients required re-interventions within the period of 7 years. Noteworthy, despite the efficacy of procedures in the treatment of fibroids, new lesions might have developed during such a long period. A similar situation could also take place in myomectomies. Despite the removal of single fibroids, new or already present small fibroids can develop. The advantage of UEF is the fact that during one procedure all fibroids are treated, even those of several millimetres, which prevents their further development. The only way protecting against the development of new fibroids is hysterectomy.

There are still no explicit data regarding the course of pregnancy after uterine artery embolisation. However, a few studies demonstrated increased numbers of problems after such procedures. UAE was usually compared to laparoscopic myomectomy. Based on this comparison, higher incidences of miscarriages and premature deliveries were described. Moreover, an increased number of improperly placed placenta was observed. Furthermore, a higher number of postpartum haemorrhages was noted (30). The fault of the above studies could have been the fact that patients with single, not large fibroids were qualified for myomectomies; patients undergoing selection for embolisation, due to a high number of or large fibroids could not be qualified for fibroid removal but for hysterectomy, which was the option unacceptable for patients. In their cases, UEF was the last chance option.

Based on his observations, McLucas (30) noted that pregnancy after uterine artery embolisation is a real option for women above the age of 40 years. His study encompassed 44 patients who chose embolisation as a sparing method giving the chance to preserve fertility. Twenty-eight pregnancies were noted in 22 patients. In the study group, there were no cases of intrauterine growth retardation in the prenatal period, foetal insufficiency during delivery and problems associated with the uterine muscle itself. The conception rate was 47.7%. In the study by Pisco, 74 patients chose UFE considering the preservation of fertility;

44 patients (mean age of 36 years) conceived, which corresponds to the fertility rate of 59.5% (31).

In metaanalysis from 2012 by Toor S. et al. (32.). Author conclude that fifty-four study populations met the inclusion criteria, yielding a total of 8159 patients. Major complications occurred at a rate of 2.9%. The rate of hysterectomy for resolution of a complication from UAE was 0.7% and the rate of readmission was 2.7%. Permanent amenorrhea was recorded in 3.9%. Which means that symptomatic uterine leiomyoma treatment

by UAE is an effective procedure with a low rate of major complications supporting its use as an alternative to hysterectomy (32).

CONCLUSIONS

UAE is a safe and effective treatment for symptomatic uterine fibroids. In addition to reducing the symptoms, significantly reduces their volume. The key to success is proper qualification, as well as cooperation between the radiologist and the gynecologist.

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